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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,503	10/29/2003	Gabriel Keita	ESOA:002US	5749

32425 7590 11/22/2006

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EXAMINER	
LAMBELET, LAWRENCE EMILE	
ART UNIT	**PAPER NUMBER**
1732	

DATE MAILED: 11/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,503	KEITA ET AL.	
	Examiner	Art Unit	
	Lawrence Lambelet	1732	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-33* is/are rejected.

7)☒ Claim(s) *31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 31 recites the limitation "the instrument" at line 16 on page 23. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 6, 11-12, and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berlin et al (U.S. Patent 2,723,554), and further in view of Mulligan (U.S. Patent 3,355,932).

Berlin et al, hereafter "Berlin", discloses a method reading on claims 1 and 14. Berlin teaches providing a cavity having an opening sealed by a sample disk of a rubber compound separating liquid on one side from a fluid under pressure on the other side. See lines 20-36 in column 1 and Fig's 4-5. Berlin further teaches puncturing the disk and observing the pressure at which bubbles appear in the liquid. See lines 40-45 in column 1 and lines 28-31 and 43-45 in column 3.

Berlin teaches that the puncturing instrument is withdrawn, as required by claim 14. See lines 13-20 in column 3.

Berlin teaches that the cavity is a cylinder having a bottom opening, an inner wall defining a cavity space, and a disk of sample (sealing) material over the opening, as required by claim 6. See lines 1-7, 28-35, and 70-72 in column 2.

Berlin teaches that liquid is drawn into the cavity after placement of the sample material, as required by claim 12. See lines 21-25 in column 3.

Berlin does not teach applying a vacuum to create the pressure differential, as required by claims 1 and 14. Berlin further does not teach applying the vacuum by venturi, as required by claim 11. Berlin still further does not teach that the cavity has a sealed top opening, as required by claim 6.

Mulligan teaches applying a vacuum over a liquid in a seal integrity test where gas or air bubbles are indicating. See lines 48-55 in column 7, lines 18-34 in column 8 and Fig. 31. Mulligan also teaches a cylindrical cavity having a sealed top opening. See lines 32-45 in column 2. One skilled in the art would have known that a venturi is a choice of method for applying a vacuum.

Berlin and Mulligan are combinable because they are concerned with a similar technical field, namely, seal-integrity testing. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Berlin the vacuum pressurization alternative taught by Mulligan. The motivation to do so would have been to simplify apparatus by using the same cavity for both liquid vessel and pressure vessel.

Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berlin in view of Mulligan as applied to claims 1, 6, 11-12, and 14 above, and further in view of Macin et al (U.S. Patent 4,534,208).

Berlin/Mulligan teaches the method of claims 1, 6, 11-12, and 14, as discussed above.

Berlin/Mulligan does not teach cavity pressure "p" such that $10 \leq p \leq 505$ mmHg, as required by claim 2, or $75 \leq p \leq 505$ mmHg, as required by claim 3, or $p \leq 505$ mmHg, as required by claim 4.

Macin et al, hereafter "Macin", teaches that a relatively stabile pressure of 5 inHg (127 mmHg) indicates seal integrity in a vacuum test involving a membrane-sealed container. See lines 20-32 in column 4.

Berlin/Mulligan and Macin are combinable because they are concerned with a similar technical field, namely, seal-integrity testing. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Berlin/Mulligan the pressure optimization taught by Macin. The motivation to do so would have been to employ a non-destructive test procedure. See lines 44-50 in column 2 of Macin.

Claims 5, 7-9, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Berlin in view of Mulligan as applied to claims 1, 6, 11-12, and 14 above, and further in view of Su et al (U.S. Patent 6,103,148).

Berlin/Mulligan teaches the method of claims 1, 6, 11-12, and 14, as discussed above.

Mulligan teaches neoprene for a seal material, as required by claim 9. See lines 34-37 in column 2.

Berlin/Mulligan does not teach the sealing material with an opening size that self-closes, as required by claim 5. Berlin/Mulligan further does not teach repeating the procedure and testing two seal materials, as required by claim 8. Berlin/Mulligan still further does not teach that one of the materials is silicone, as required by claims 9 and 13. Berlin/Mulligan again still further does not teach that the instrument is robotically controlled, as required by claim 7. Berlin/Mulligan yet again still further does not teach tracking liquid loss through the seal opening, as required by claim 10.

Su et al, hereafter "Su '148", teaches that a gasket (sealing material) formed of silicon will be self-sealing when used in combination with an insertion needle. See lines 28-35 in column 11. Su '148 further teaches that a pneumatic cylinder (robotic control) is used to insert an insertion needle (instrument). See lines 30-53 in column 20. Su '148 still further teaches that monomer (liquid) leaking into the needle hole can be cured thereby blocking the hole. See lines 42-48 in column 11.

It would have been obvious to one of ordinary skill that such a leak would be observable, and that loss could be tracked over time by drip or level change. Furthermore, it would have been obvious to one of ordinary skill to test more than one material and assure optimization through material choice.

Berlin/Mulligan and Su '148 are combinable because they are concerned with a similar technical field, namely, self-sealing materials. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Berlin/Mulligan the choice of a silicone material as taught by Su '148. The motivation to do so would have been to avoid needless testing by pre-selection of material. See lines 20-28 in column 1 of Berlin.

Claims 15, 19-22, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keita et al (U.S. Patent 6,416,689), and further in view of Su (U.S. Patent Application Publication 2002/0047220).

Keita et al, hereafter "Keita", discloses a method reading on claims 15 and 26. Keita teaches a vertically oriented molding cavity defined by two mold pieces with an annular closure member disposed at the periphery with a check valve (seal) attached thereto positioned at the bottom into which a polymerizable composition is introduced. See lines 57-68 in column 1 and lines 1-9 in column 2.

Keita does not teach that the composition is introduced by an instrument puncturing the closure member, as required by claim 15.

Su, hereafter "Su '220", teaches that a filling needle (instrument) can be used to pierce the elastomeric sleeve (closure member). See paragraph [0017].

Keita and Su '220 are combinable because they are concerned with a similar technical field, namely, molding plastic ophthalmic lens. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Keita

the filling means of Su '220. The motivation to do so would have been to avoid leaving the valve imprisoned in the cured material and having to remove it by edge machining. See lines 1-5 in column 3 of Keita.

Keita does not teach rotating the mold about a horizontal axis, as required by claim 19, or rotating it after retraction of the instrument, as required by claim 21. Keita further does not teach rotating it 90°, even after retraction of the instrument, as required by claims 20 and 22.

Su '220 teaches that the mold has horizontal and vertical axes as well as a venting opening and a casting port. See paragraph [0010]. Su '220 further teaches that the venting opening is located on the vertical axis at the uppermost point, and that the opening and port are spaced at an angle placing them both in the upper portion of the mold. See paragraph [0015]. This orientation requires that a bottom port be rotated about the horizontal axis to achieve an elevated position. Su '220 still further teaches that the angle can have a value between 0 to 90°, implying a rotational angle of at least 90° from a dead bottom location. See paragraph [0043]. It would have been obvious to one of ordinary skill to remove the filling instrument prior to rotating the mold in order to prevent damage or leakage to the instrument or seal.

Keita and Su '220 are combinable because they are concerned with a similar technical field, namely, molding plastic ophthalmic lens. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Keita the location of the filling and venting apertures as taught by Su '220. The motivation to

do so would have been to avoid having bubbles pass through the optically active area of the lens. See paragraph [0011] of Su '220.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keita in view of Su '220 as applied to claims 15, 19-22, and 26, and further in view of Berlin in view of Mulligan and Macin as applied to claims 1-4, 6, 11-12, and 14.

Keita/Su '220 teaches the method of claims 15, 19-22, and 26, as discussed above. Berlin/Mulligan/Macin teaches the method of claims 1-4, 6, 11-12, and 14, as discussed above.

Keita/Su '220 does not teach that the seal material, when tested using the method of claim 1, yields a cavity pressure "p" such that $10 \leq p \leq 505$ mmHg, as required by claim 16, or $75 \leq p \leq 505$ mmHg, as required by claim 17.

Berlin teaches providing a cavity having an opening sealed by a sample disk of a rubber compound separating liquid on one side from a fluid under pressure on the other side. See lines 20-36 in column 1 and Fig's 4-5. Berlin further teaches puncturing the disk and observing the pressure at which bubbles appear in the liquid. See lines 40-45 in column 1 and lines 28-31 and 43-45 in column 3.

Mulligan teaches applying a vacuum over a liquid in a seal integrity test where gas or air bubbles are indicating. See lines 48-55 in column 7, lines 18-34 in column 8 and Fig. 31.

Macin teaches that a relatively stabile pressure of 5 inHg (127 mmHg) indicates seal integrity in a vacuum test involving a membrane-sealed container. See lines 20-32 in column 4.

Keita/Su '220 and Berlin/Mulligan/Macin are combinable because they are concerned with a similar technical field, namely, seal-integrity. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Keita/Su the test methodology of Berlin/Mulligan/Macin. The motivation to do so would have been to verify elimination of the valve by substitution of a needle-punctured seal. See lines 1-5 in column 3 of Keita.

Claims 18, 23, and 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keita in view of Su '220 as applied to claims 15, 19-22, and 26, and further in view of Su '148.

Keita/Su '220 teaches the method of claims 15, 19-22, and 26, as discussed above.

Keita/Su '220 discloses a method reading on claim 31. Keita teaches a vertically oriented molding cavity defined by two mold pieces with an annular closure member disposed at the periphery and a check valve (seal) attached thereto positioned at the bottom into which a polymerizable composition is introduced. See lines 57-68 in column 1 and lines 1-9 in column 2. Keita further teaches that one mold piece has a concave surface and the other mold piece has a convex surface, as further required by claim 31. See Fig. 1.

Su '220 teaches that a filling needle (instrument) can be used to pierce the elastomeric sleeve (closure member). See paragraph [0017]. Su '220 further teaches that the mold has horizontal and vertical axes as well as a venting opening and a casting port. See paragraph [0010]. Su '220 still further teaches that the venting opening is located on the vertical axis at the uppermost point, and that the opening and port are spaced at an acute angle. See paragraph [0015]. This orientation requires that a bottom port be rotated about the horizontal axis. It would have been obvious to one of ordinary skill to remove the filling instrument prior to rotating the mold in order to prevent damage or leakage to the instrument or seal.

Su '220 teaches that the lens-forming material is hardened (polymerized) to form an optical lens, as required by claims 23 and 31. See paragraph [0010].

Keita/Su '220 does not teach retraction of the instrument and self-sealing of the opening, as required by claims 18 and 31. Keita/Su '220 further does not teach that the sealing material is silicone, as required by claim 30.

Su '148 does teach that a material formed of silicon self-seals when the puncture is made by a syringe needle. See lines 28-35 in column 11.

Keita/Su '220 and Su '148 are combinable because they are concerned with a similar technical field, namely, sealing materials. One of ordinary skill at the time of the invention would have found it obvious to include in the method of Keita/Su '220 the leak-resistant material choice taught by Su '148. The motivation to do so would have been to find a substitution for the valve. See lines 1-5 in column 3 of Keita.

Claims 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keita in view of Su '220 as applied to claims 15, 19-22, and 26, and further in view of Reed et al (U.S. Patent Application 2004/0021238).

Keita modified by Su '220 teaches the method of claims 15, 19-22, and 26, as discussed above.

Keita/Su '220 does not teach a vent tape positioned at the top, as required by claim 24, or that the tape be permeable to air but not to polymerizable material, as required by claim 25.

Reed et al, hereafter "Reed", teaches a gas-permeable-liquid-impermeable tape. See paragraph [0030].

Keita/Su '220 and Reed are combinable because they are concerned with a similar technical field, namely, molding plastic lens. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Keita/Su '220 the vent tape taught by Reed. The motivation to do so would have been to avoid overfilling of the molding cavity. See paragraph [0013] of Reed.

Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keita in view of Su '220 as applied to claims 15, 19-22, and 26, and further in view of Wires (U.S. Patent Application 2003/0214060)..

Keita modified by Su '220 teaches the method of claims 15, 19-22, and 26, as discussed above.

Keita/Su '220 does not teach polymerizing within four minutes, as required by claim 27, or within seven minutes, as required by claim 28, or within ten minutes, as required by claim 29.

Wirés teaches a curing time of ten minutes or less. See claim 41 of the reference.

Keita/Su '220 and Wires are combinable because they are concerned with a similar technical field, namely, molding plastic lens. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Keita/Su '220 the polymerization time of Wires. The motivation to do so would have been to increase cycle time by reducing lengthy cure time. See paragraph [0007] of Wires.

Claims 32-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Keita in view of Su '220 and Su '148 as applied to claims 15, 18-23, 26, and 30-31, and further in view of Berlin in view of Mulligan and Macin as applied to claims 1-4, 6, 11-12, and 14.

Keita/Su '220/Su '148 teaches the method of claims 15, 18-23, 26, and 30-31, as discussed above.

Keita/Su '220/Su '148 does not teach that the seal material, when tested using the method of claim 1, yields a cavity pressure "p" such that $10 \leq p \leq 505$ mmHg, as required by claim 32, or $75 \leq p \leq 505$ mmHg, as required by claim 33.

Berlin teaches providing a cavity having an opening sealed by a sample disk of a rubber compound separating liquid on one side from a fluid under pressure on the other

side. See lines 20-36 in column 1 and Fig's 4-5. Berlin further teaches puncturing the disk and observing the pressure at which bubbles appear in the liquid. See lines 40-45 in column 1 and lines 28-31 and 43-45 in column 3.

Mulligan teaches applying a vacuum over a liquid in a seal integrity test where gas or air bubbles are indicating. See lines 48-55 in column 7, lines 18-34 in column 8 and Fig. 31.

Macin teaches that a relatively stabile pressure of 5 inHg (127 mmHg) indicates seal integrity in a vacuum test involving a membrane-sealed container. See lines 20-32 in column 4.

Keita/Su '220/Su '148 and Berlin/Mulligan/Macin are combinable because they are concerned with a similar technical field, namely, seal-integrity for cast molding. One of ordinary skill in the art at the time of the invention would have found it obvious to include in the method of Keita/Su '220/Su '148 the test methodology of Berlin/Mulligan/Macin. The motivation to do so would have been to verify elimination of the valve by substitution of a needle-punctured seal. See lines 1-5 in column 3 of Keita.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lawrence Lambelet whose telephone number is 571-272-1713. The examiner can normally be reached on 8 am-4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on 571-272-1176. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LEL
11/14/2006

CHRISTINA JOHNSON
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11/16/06